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EXAMINER

RAO, MANJUNATH N

ART UNIT PAPER NUMBER

1652

DATE MAILED: 08/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/807,933

Applicant(s)

NAKAMURA ET AL.

Examiner

Manjunath N. Rao, Ph.D.

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-56 and 58-85 is/are pending in the application.
- 4a) Of the above claim(s) 1-36, 41-56, 58 and 59 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 37-40 and 60-85 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 April 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claims 1-56, 58-85 are currently pending in this application. Claims 37-40 and 60-85 are now under consideration. Claims 1-36, 41-56, 58-59 remain withdrawn from consideration as being drawn to non-elected invention.

Election/Restrictions

Applicant's election with traverse of Group XIII, Claims 37-40 in Paper No. 14 is acknowledged. The traversal is on the ground(s) that coexamination claims 60-85 as a part of group XIII is necessary. Accordingly Examiner has included claims 60-85 in the elected group.

The requirement of restriction of the remaining is still deemed proper and is therefore made FINAL.

Claims 1-36 and 41-56, 58-59 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in Paper No. 14.

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d).

Drawings

Drawings submitted in this application are accepted by the Examiner for examination purposes only.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 37-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 37-38 recite the phrase "derived from a filamentous fungus". The metes and bounds of this phrase is not clear to the Examiner. Literally, while the term "derived" means "to isolate from or obtain from a source", the above term could also mean "to arrive at by reasoning i.e., to deduce or infer" or also mean "to produce or obtain from another substance". Therefore, it is not clear to the Examiner either from the specification or from the claims as to what applicants mean by the above phrase. It is not clear to the Examiner whether the endoglucanase "derived from a filamentous fungus" encompasses only those endoglucanases isolated from fungi or whether it encompasses recombinants, variants and mutants of any endoglucanase from any or all other sources and labeled as "derived from a filamentous fungus". As applicants have not provided a definition for the above phrase, Examiner has interpreted the claims broadly to mean, endoglucanase "derived from a filamentous fungus" encompasses any endoglucanase from any or all sources. Examiner has given the same interpretation while considering the claims for all other rejections.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Art Unit: 1652

Claims 37-40, 60-85 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an endoglucanase enzyme with SEQ ID NO:1, 3, 5, 7, 9 or 11, encoded by polynucleotides with SEQ ID NO:2, 4, 6, 8, 10 or 12 or 13 does not reasonably provide enablement for any or all endoglucanases including modified endoglucanases or homologues of said endoglucanases or any endoglucanase having a cellulose binding domain (CBD) as claimed in claim 38, polynucleotides encoding such endoglucanases (including polynucleotides which comprise a sequence in which codons have been optimized for a host by selecting frequently used codons of that host), methods of using such enzymes and compositions comprising such enzymes. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in *In re Wands* (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claim(s).

Claims 37-40 and 60-85 are so broad as to encompass any endoglucanase from any source. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of endoglucanases broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid

Art Unit: 1652

sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to the endoglucanases with amino acid sequence SEQ ID NO:1, 3, 5, 9, or 11.

Furthermore, while applicants have taught the polynucleotides with SEQ ID NO:2, 4, 6, 8, 10, 12, or 13, they have not taught polynucleotides encoding endoglucanases in which codons are optimized for any or all the host cells one of skilled in the art can use. It would require undue experimentation of the skilled artisan to make and use the claimed polypeptides and polynucleotides. The specification is limited to teaching use of SEQ ID NO: 1, 3, 5, 9, or 11 encoded by SEQ ID NO:2, 4, 6, 8, 10 12, or 13 as a endoglucanase but provides no guidance with regard to the making of variants and mutants and homologues or with regard to other uses. In view of the great breadth of the claim, amount of experimentation required to make the claimed polypeptides, the lack of guidance, working examples, and unpredictability of the art in predicting function from a polypeptide primary structure (e.g., see Ngo et al. in *The Protein Folding Problem and Tertiary Structure Prediction*, 1994, Merz et al. (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495, Ref: U, Form-892), the claimed invention would require undue experimentation. As such, the specification fails to teach one of ordinary skill how to use the full scope of the polypeptides encompassed by this claim.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a

Art Unit: 1652

reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass all modifications and fragments of any endoglucanase or endoglucanase with SEQ ID NO: 1, 3, 5, 9, or 11 and their respective polynucleotides encoding the same because the specification does not establish: (A) regions of the protein structure which may be modified without effecting endoglucanase activity; (B) the general tolerance of endoglucanases to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any endoglucanase amino acid residue with an expectation of obtaining the desired biological function; (D) methods to optimize codons for use in any or all types of host cells; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including endoglucanases with an enormous number of amino acid modifications of the endoglucanase of SEQ ID NOS:1, 3, 5, 9 or 11 and the polynucleotides encoding such enzymes. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of endoglucanases and their respective polynucleotides encoding the same having the desired biological characteristics is unpredictable and the experimentation left to those skilled

Art Unit: 1652

in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claims 37-40 and 60-85 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 37-40, 60-85 are directed to endoglucanases derived from fungi, modified endoglucanases, and homologues of the same and the respective polynucleotides encoding the same. Claims 37-40, 60-85 are rejected under this section of 35 USC 112 because the claims are directed to a genus of polypeptides and polynucleotides derived from fungi or derived from SEQ ID NO:1, 3, 5, 7, 9, or 11 including modified polypeptide sequences, modified by at least one of deletion, addition, insertion and substitution of an amino acid residue that have not been disclosed in the specification. No description has been provided of the modified/homologue polypeptide and polynucleotide sequences encompassed by the claim. No information, beyond the characterization of SEQ ID NO:1-12 and 13 has been provided by applicants which would indicate that they had possession of the claimed genus of modified polypeptides and polynucleotides encoding the same. The specification does not contain any disclosure of the structure of all the derived polypeptide sequences or modified sequences, including fragments and variants and polynucleotides encoding the same within the scope of the claimed genus. The genus of polypeptides claimed and their respective polynucleotides encoding the same is a large variable genus including peptides/polynucleotides which can have a wide variety of structures. Therefore many structurally unrelated polypeptides and polynucleotides are encompassed within the scope of these claims. The specification discloses only few species of the claimed genus which is insufficient to put one of skill in the art in possession of the attributes and features of all

Art Unit: 1652

species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 37-38, 40, 60-85 are rejected under 35 U.S.C. 102(b) as being anticipated by Schulein et al. (WO94/07998, April, 1994). This rejection is based upon the public availability of a printed publication. Claims 37-38, 40 and 60-85 of the instant application are drawn to endoglucanases derived from fungi and belonging to family 45, or modified endoglucanases of SEQ ID NO:1, 3, 5, 7, 9, 11 encoded by SEQ ID NO:2, 4, 8, 10, 12-13, vectors and host cells comprising the same method of making the polypeptide and methods of use of the endoglucanase in a variety of processes such as detergent, fabric color restoration, fuzz removal, deinking process, paper pulp treatment and in making animal feeds. Schulein et al. disclose an endoglucanase derived from fungi and belonging to family 45 and its use in a variety of processes as claimed in the above claims. Since there is no limitation placed on the number of changes that can be present in the amino acid sequence with SEQ ID NO:1, 3, 5, 7, 9, or 11 and the nucleotide changes in the

Art Unit: 1652

polynucleotide sequence, SEQ ID NO:2, 4, 6, 8,10, 12, 13, for a variant polypeptide/
polynucleotide, claims 37-40 and 60-85 read on the endoglucanase and the encoding DNA
sequence disclosed by Schulein et al. Thus Schulein et al. anticipate claims 20-25 of this
application as written.

Claims 37-40, 72-73 are rejected under 35 U.S.C. 102(b) as being anticipated by Yu et al. (US
4,966,850, Oct 30, 1990). This rejection is based upon the public availability of a patent. Claims
37-40, 72-73 of the instant application drawn to endoglucanases derived from filamentous fungi
and belonging to family 45, having a CBD in its N-terminal region, wherein the filamentous
fungi belong to genus *Rhizopus*, *Mucor* or *Phycomyces* and a composition comprising said
enzyme. Yu et al. disclose an endoglucanase composition isolated from *Mucor sp.* (see column
14, and Tables 9 through 11). While the reference does not explicitly disclose that the
endoglucanase belongs to family 45 or that it has an N-terminal CBD, Examiner takes the
position that the enzyme disclosed in the reference and that claimed are inherently one and the
same as the reference enzyme is isolated from *Mucor sp.* Therefore, Yu et al. anticipate claims
37-40, 72-73 as written.

Since the Office does not have the facilities for examining and comparing applicants'
protein with the protein of the prior art, the burden is on the applicant to show a novel or
unobvious difference between the claimed product and the product of the prior art (i.e., that the
protein of the prior art does not possess the same material structural and functional
characteristics of the claimed protein). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA
1977) and *In re Fitzgerald et al.*, 205 USPQ 594.

Art Unit: 1652

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 37-40, 60-74, 77, 78, 80-81, 82 are rejected under 35 U.S.C. 102(e) as being anticipated by Schulein et al. (US6387690, May 14, 2002). This rejection is based upon the public availability of a patent. Claims 37-40, 60-74, 77, 78, 80-81, 82 of the instant application drawn to endoglucanases derived from filamentous fungi and belonging to family 45, having a CBD in its N-terminal region, wherein the filamentous fungi belong to genus *Rhizopus*, *Mucor* or *Phycomyces*, polynucleotides encoding the endoglucanase and vectors and host cells that can be used to transform along with a method of producing the polypeptide. Claims are also drawn to method of using the enzyme in restoration of color to the fabric by using the enzyme as an additive to detergents and its use in treating fabrics. Schulein et al. disclose an endoglucanase isolated from *Phycomyces niteus* (see entire document specifically claim 1). The reference also discloses polynucleotides encoding the endoglucanase and vectors and host cells that can be used to transform along with a method of producing the polypeptide. The reference discloses method of using the enzyme in restoration of color to the fabric by using the enzyme as an additive to detergents and its use in treating fabrics. While the reference does not explicitly disclose that the endoglucanase belongs to family 45 or that it has an N-terminal CBD, Examiner takes the position that the enzyme disclosed in the reference and that claimed are inherently one

Art Unit: 1652

and the same as the reference enzyme is isolated from *Phycomyces* sp. Therefore, Schulein et al. anticipate claims 37-40, 60-74, 77, 78, 80-81, 82 as written.

Since the Office does not have the facilities for examining and comparing applicants' protein with the protein of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same material structural and functional characteristics of the claimed protein). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 60-71, 74-85 rejected under 35 U.S.C. 103(a) as being unpatentable over Yu et al. as applied to claims 37-40 and 72-73 above, and further in view of Schulein et al. (WO 94/07998, 1994 or US 6,378,690 B1, May 2002). Claims 60-71, 74-85 are drawn to polynucleotide encoding the modified endoglucanase or that isolated from *Mucor sp.* vectors and host cells comprising the same and methods of use of the enzyme in a variety of processes. The reference of Yu et al. disclosing the endoglucanase from *Mucor sp.* has already been discussed above. However, the reference Yu et al. does not teach the polynucleotides, vectors and host cells and methods of making the enzyme and use of the enzyme.

Schulein et al. also teach the isolation of an endoglucanase and manipulation of the polynucleotide encoding the same and method of making the polypeptide along with the variety of uses for the enzyme.

Therefore, with the availability of a new enzyme taught by Yu et al. it would have been obvious to those skilled in the art to use the methods taught by Schulein et al. to isolate the polynucleotide encoding the above enzyme, transfer it to vectors and transform host cells such as Yeasts or to other filamentous cells as taught by Schulein et al., make the recombinant enzyme and use the enzyme in a variety of applications all of which are again taught by Schulein. One of ordinary skill in the art would have been motivated to do so as Yu et al. teach that these are thermostable enzymes capable of withstanding the higher temperature. One of skill in the art would have a reasonable expectation of success since Yu et al. provide the composition comprising the enzyme isolated from *Mucor sp.* and Schulein et al. provide the teachings to isolate the polynucleotide and manipulate the same for recombinant process. Therefore the above invention would have been *prima facie* obvious to those skilled in the art.

Conclusion

None of the claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manjunath N. Rao, Ph.D. whose telephone number is 703-306-5681. The examiner can normally be reached on 7.30 a.m. to 4.00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone


Application/Control Number: 09/807,933

Page 13

Art Unit: 1652

numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-306-0196.



MANJUNATH RAO
PATENT EXAMINER

Manjunath N. Rao
August 15, 2003